improved long-term outcomes due to the nephrotoxic effect of CNI regimens. A sirolimus-based CNI withdrawal regimen may maximize the likelihood of long-term graft and patient survival. The goal of this study is to evaluate the cost-effectiveness of sirolimus regimen (sirolimus+cyclosporinewithdrawal at three-month+steroid) compared with tacrolimus + mycofenolate mofetil(MMF) + Steroid regimen, and cyclosporine + MMF + steroid regimen in renal transplant patients in Korea. **METHODS:** A Markov model simulates costs and outcomes in a hypothetical cohort of renal transplant patients for 20 years with 5% discount rate. The model contain five health states: patient with graft survival, patient with graft failure, patient with regraft survival, patient with regraft failure and patient death. Short and long-term outcomes and utility weights were obtained from published literature, and quality adjusted life years (QALYs) were used as an effectiveness measure. Resource utilizations and direct costs were calculated with the Korean public institutional data and clinical expert opinions. Sensitivity analyses were performed on crucial parameters. **RESULTS:** Sirolimus regimen costs US$144,894 for the 8.055 QALYs for 20 years treatment duration, whereas US$173,234 for 6.399 QALYs for tacrolimus, and US$151,286 for 5.567 QALYs for cyclosporine. Sirolimus regimen was shown to be dominant, as it was more efficacious in QALYs and less costly than tacrolimus and cyclosporine regimen. The results from the sensitivity analysis showed that the results were quite robust across most parameters. Cost effectiveness was most sensitive to model duration. **CONCLUSIONS:** Sirolimus regimen shows not only potential clinical benefits for long-term but also is expected to be cost-saving over a patient's life compared with the most frequently prescribed CNI regimens in Korea.

PUK11

AN ECONOMIC EVALUATION OF FESOTERODINE IN THE TREATMENT OF OVERACTIVE BLADDER (OAB) IN KOREA

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OBJECTIVES: This study was conducted to evaluate the cost-effectiveness of Fesoterodine compared with Tolterodine in the treatment of OAB in Korea. The evaluation was performed from the perspective of the statutory health insurer who will cover the direct costs of the drug upon approval and from societal viewpoint, as well. **METHODS:** Through a systematic review of preceding literature, we firstly figured out the factors that determine the efficacy for Fesoterodine and Tolterodine and secondly investigated whether Fesoterodine decreases symptom of OAB patients from randomized comparative trials with various comorbidities. Since there is no clinical dataset of Fesoterodine along with Tolterodine for OAB patients in Korea, this study indirectly adopted the determinants and probabilities from the clinical results in all languages for OAB treatment in order to estimate the treatment outcomes of the selected comparators, and conducted the probabilistic sensitivity analysis. This study also used to explore the cost-effectiveness of Fesoterodine in the following comorbidities: fracture, UTI, and depression. **RESULTS:** Based on the computed clinical success at week 12 of OAB treatment, Fesoterodine has higher performance than Tolterodine by 18.44% point (56.50% vs. 38.06%) with a bit more total medical cost, though (KRW 306,855 vs. KRW 260,457). In terms of cost-effectiveness ratio (CER), Fesoterodine has lower value than Tolterodine (KRW 5,431 vs. KRW 6,843), which implies that Fesoterodine is more cost-effective than Tolterodine in OAB treatment. Through the one-way sensitivity analysis varying the values of several controversial parameters such as resolution of incontinence, pad usage and frequency, and unit price of pad, we could not find the reversal case in which Tolterodine outweighs Fesoterodine. **CONCLUSIONS:** Probabilistic analysis showed that OAB treatment with Fesoterodine is cost-effective in Korea compared to Tolterodine.

PUK12

CLINICAL AND ECONOMIC EVALUATION OF OVERACTIVE BLADDER PATIENTS (OAB) FAILLING TO CONSERVATIVE MANAGEMENT IN SPAIN: A FOUR HOSPITAL BASED ECONOMIC MODEL

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OBJECTIVES: Overactive bladder (OAB) is a dysfunction of the lower urinary tract which causes significant impairment to patients' QoL. Our study aim was to assess the cost-effectiveness profile of Sacral neuromodulation (SNM), botulinum neurotoxin (BoNT) and optimized medical treatment (OMT) in symptomatic idiopathic OAB patients with OMT experience in Spain. **METHODS:** A decision-analytic model was built to simulate the clinical and economic consequences of initiating treatment for idiopathic OAB with SNM, BoNT or continue with OMT. Effectiveness (defined in terms of 'improvement', number of urinary incontinence episode and utility values) and model probabilities were obtained from literature; treatment pathways after initial failure, resource use and assumptions were derived from local expert opinion. Due to the lack of mid-long term efficacy data of BoNT, the most conservative assumptions were included. The model was adjusted for a ten-year follow-up, to include the neurostimulator battery change for SNM. Costs and effects were discounted at 3%. **RESULTS:** OAB management with SNM may be associated with €12.18 and €2.62 and per episode avoided and incremental cost-effectiveness ratios (ICERs) of 23,570€ and 1,573€ per Quality Adjusted Life Years (QALY) gained compared to OMT, at 1 and 10 years respectively. SNM may also have a higher mid-long term effectiveness than BoNT at a reasonable cost, with ICERs of €29,450 and 9,287€ per QALY gained at year 4 and 10, respectively. Probabilistic sensitivity analysis showed the robustness of the results in SNM vs OMT, and due to the lack of BoNT efficacy data availability, an important variability in the results of SNM vs BoNT. **CONCLUSIONS:** SNM is effective in the treatment of OAB at a reasonable cost versus BoNT and OMT in Spain. Further research is needed to assess the BoNT mid-long term effectiveness to confirm the comparison versus SNM.

PUK13

COST-EFFECTIVENESS OF A RENAL HEALTH PROGRAM IN PATIENTS WITH HYPERTENSIVE AND/OR DIABETES INDUCED CHRONIC KIDNEY DISEASE

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OBJECTIVES: To evaluate the impact of a hypothetical renal health program (RHP) designed to delay initiation of renal replacement therapy (RRT). **METHODS:** We used a Markov model and Monte Carlo technique to simulate two simultaneous 1000 patient cohorts assigned to a renal health program (RHP) or to "standard care" (SC). Population consisted of patients with hypertension and/or diabetes, with initial glomerular filtration rate (GFR) between 60 and 15 ml min (stages 3 and 4 of chronic kidney disease [CKD]). We assumed that RHP had a monthly cost of two to four times that of SC, and that it reduced GFR loss in a proportion that we called "the RHP effect". The model incorporated 47 variables: 20 epidemiologic variables, 19 cost variables (all at local Colombian rates) and 8 quality of life variables (we used QALY established through experts' consensus). We used a third-party payer perspective, a 5-year time frame and a 3% annual discount rate both for costs and for utilities. **RESULTS:** Assuming a RHP 0.8 effect (equivalent to a 20% GFR loss reduction) the average cost per patient was US$ 17,680 in RHP and US$ 15,560 in SC. Average utility was higher in RHP (3.53 QALY) than in SC (3.45 QALY). From the total of 1000 patients of the RHP group, 101 died compared with 124 in the SC group. Additionally, along the five-year period, 242 subjects from the RHP group required RRT compared with 310 from the SC group. Based on these results, US$ 90,950 would be paid per death averted, US$ 27,200 per RRT averted and the incremental cost-effectiveness ratio would be US$ 21,450 per QALY gained. **CONCLUSIONS:** Five years is a short time. Return to investment would be seen only in patients with advanced CKD. However, a RHP with a modest effect would still de cost-effective.

URINARY/KIDNEY DISORDERS – Patient-Reported Outcomes Studies

PUK15

QUALITY OF LIFE IN A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF OXYBUTYNIN CHLORIDE TOPICAL GEL TREATMENT OF PATIENTS WITH OVERACTIVE BLADDER

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OBJECTIVES: To determine the effects of oxybutynin chloride topical gel (OTG), a novel 10% ethanolic formulation, on health-related quality of life (HRQoL) in adults with overactive bladder (OAB). **METHODS:** Women and men aged ≥18 years with urge urinary incontinence were enrolled at 76 centers in a randomized, double-blind, placebo-controlled, parallel-group study (00350636 at clinicaltrials.gov). Patients applied 1 g OTG once daily or matching placebo gel for up to 12 weeks. To assess HRQoL, investigators asked patients to complete 2 disease-specific questionnaires (Incontinence Impact Questionnaire [IIQ]; King's Health Questionnaire [KHQ]) at baseline and weeks 1, 4, 8, and 12. Effects of OTG on HRQoL were assessed by computing mean change in questionnaire scores from baseline to week 12 or last observation. Differences between active and placebo treatment were compared by analysis of covariance. **RESULTS:** In this study completed May 2007, 704 women and 85 men were enrolled; 389 patients received OTG and 400 received placebo. IIQ total score improved significantly more in patients treated with OTG (mean change, −72.1 points; P = .0005) than in those receiving placebo (mean change, −49.5 points). OTG also improved HRQoL significantly more (P ≤ .0078) than did placebo in all 4 IIQ subscales (Travel, Physical Activity, Social Relationships, and Emotional Health). Mean KHQ scores improved significantly more (P ≤ .0489) with OTG than with placebo in 6 of 10 domains, many directly associated with OAB symptoms (Incontinence Impact, Symptom Severity, Role Limitations, Personal Relationships, Sleep/Energy, and Severity [Coping] Measures). Dry mouth was the most common treatment-related adverse event in patients given OTG (27/389; 6.9%), but was not a primary reason for any patient to stop treatment. **CONCLUSIONS:** OTG treatment significantly improved HRQoL in adults with OAB.